REMARKS

This is intended to be a complete response to the Final Office Action mailed on May 16, 2008, (the "Final Office Action") and the Advisory Action Before the Filing of an Appeal Brief mailed August 18, 2008, (the "Advisory Action") in which claims 29-31, 35, 37 and 38 were rejected. Based on discussions with the Examiner and the Supervisor Examiner Joseph Woitach during the telephonic interview on May 13, 2008, and in order to present rejected claims in form for allowance, Applicants have amended independent claim 29 and have added new claims 39 and 40. Independent claim 29 is amended to include the limitations that the vector encoding ferritin-H is inserted *in vitro* and the ferritin-H produced activates production of gamma-globin proteins in the cell, and new claim 39 calls for the ferritin-H produced to bind to at least one of the 5′ and 3′ regions of the gamma-globin gene of the human beta-globin producing cell and stimulate transcription thereof. Support for the amendments can be found in the originally filed application at Page 24, lines 16-18; and Page 46, lines 3-12 and in the published application at paragraphs [0061] and [0123].

Claim Rejections – 35 U.S.C. § 112

In the Final Office Action, the Examiner has rejected the inventors' claims under § 112, first paragraph, as failing to comply with the enablement requirement. The Examiner states that, "Although the amended

claims do not recite a method for treating sickle cell disease, given the broadest reasonable interpretation in light of the specification, instant claims implicitly encompass the embodiment of treating a sickle cell disease, particularly in view of the claim language encompass[ing] a process *in vivo*. Further in light of the specification, the real world utility for repressing production of beta-globin in a cell is for therapeutic purpose for treating sickle cell disease."

Again, Applicants respectfully traverse the rejection. The limitation of treating sickle cell disease should clearly not be read into the present claims. The specification describes and teaches "a method for repressing production of beta-globin proteins and increasing production of gamma-globin proteins in a human cell," wherein the method includes "providing at least one human beta-globin producing cell; providing a vector encoding ferritin-H; and inserting the vector encoding ferritin-H into the at least one beta-globin producing cell, whereby ferritin-H is produced in the cell, and the ferritin-H produced represses production of beta-globin proteins in the cell, and activates production of gamma-globin proteins in the cell." Sufficient written description to support and enable the claim limitations can be found in the original Published Specification at paragraphs [0068] and [0086] describing the human beta-globin producing cell; paragraph [0104] describing a vector encoding ferritin-H; paragraphs [0070]-[0079], [0081], [0091], [0092],

Figs. 2B-4D and in particular paragraph [0121] and Fig. 6 describing inserting the vector encoding ferritin-H into the at least one beta-globin producing cell, whereby ferritin-H is produced in the cell, and the ferritin-H represses production of beta-globin proteins in the cell as in claim 29 and that the ferritin-H produced binds to the promoter region of the beta-globin gene of the beta-globin producing cell at -148 to -153 bp from the transcription start site of the promoter region and represses production of beta-globin proteins in the cell as called for in new dependent claim 40; and paragraphs [061] and [123] describing ferritin-H activating production of gamma-globin proteins in the cell. Applicants strongly traverse the Examiner's assertion that "given the broadest reasonable interpretation in light of the specification, instant claims **implicitly encompass** the embodiment of treating a sickle cell disease" (emphasis added). Such reasoning is simply not allowed; "while ... claims are to be interpreted in light of the specification and with a view to ascertaining the invention, **it does not follow that limitations from the specification may be read into the claims.**" (emphasis added) *Comark Communications v Harris Corp.*, 156 F.3d 1182, 1186 (Fed. Cir. 1998), *citing E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co.,* 849 F.2d 1430, 1433 (Fed. Cir. 1988). " 'Reading a claim in the light of the specification,' to thereby interpret limitations explicitly recited in the claim, is a quite different thing from 'reading

limitations of the specification into a claim,' to thereby narrow the scope of the claim by implicitly adding disclosed limitations which have no express basis in the claim." *In re Charles D. Prater and James Wei*, 415 F.2d 1393, 1395 (C.C.P.A. 1969). Similarly, the Examiner's assertion regarding "real world utility" is also irrelevant. The claims do not recite "treating sickle cell disease;" the claims recite "a method for repressing production of beta-globin proteins and increasing production of gamma-globin proteins in a human cell," and such term is fully supported in the written description.

However, in order to expedite issuance of a patent, Applicants have amended independent claim 29 to "inserting, *in vitro*, the vector encoding ferritin-H...." The Applicants respectfully assert that the examples and figures given in the specification are clearly sufficient to convince a person of skill in the art that the inventor possessed the invention and to enable such a person to repress production of beta-globin proteins and increase production of gamma-globin proteins in a human cell in the manner claimed and without undue experimentation. Therefore, Applicants respectfully request reconsideration and withdrawal of the 35 U.S.C. 112, first paragraph rejection of the claims.

Claim Rejections – 35 U.S.C. § 102 and § 103

In the Final Office Action, the Examiner withdrew the prior rejection of claims 29-31 and 33-36 under 35 U.S.C. 102(b) as being anticipated by

Picard et al. (Blood 1996; 87:2057-2064); however, claims 29-31, 35, 37 and 38 were rejected under 35 U.S.C. 103(a) as being unpatentable over *Picard et al.* The Examiner reasoned that although *Picard et al.* do not explicitly teach that β-globin protein production would be repressed, it would have been reasonably suggested to one skilled in the art. In addition the Examiner reasoned that although *Picard et al.* used mouse cells and mouse Ferritin-H rather than human cells and human Ferritin-H, it was well known in the art that the ultimate goal of animal studies was for treating diseases in humans, and hence it would have been suggested to one skilled in the art to further the studies in human cells using human ferritin-H.

Applicants respectfully traverse the rejection; however, in an effort to expedite allowance, the Applicants have amended independent claim 1 to include the limitation that the ferritin-H produced activates production of gamma-globin proteins in the cell. During the telephonic interview on May 13, 2008, Supervisor Joseph Woitech suggested that addition of this limitation should produce a patentable claim providing the prior art did not teach or suggest a method for repressing production of beta-globin proteins **and increasing production of gamma-globin proteins in a human cell**, wherein the method includes providing at least one human beta-globin producing cell; providing a vector encoding ferritin-H; and inserting the vector encoding ferritin-H into the at least one beta-globin producing cell,

whereby ferritin-H is produced in the cell, and the ferritin-H produced represses production of beta-globin proteins in the cell, **and activates production of gamma-globin proteins in the cell**. The mouse cells tested in *Picard et al.* do not produce gamma-globin proteins and are therefore not capable of being activated to produce gamma-globin proteins and could not therefore suggest or make obvious Applicants' independent claim 1.

Applicants respectfully request reconsideration and withdrawal of the 35 U.S.C. 103(a) rejection of the claims as amended.

CONCLUSION

In view of the above amendments and remarks, Applicants submit that the Examiner's rejections under 35 U.S.C. § 112 and 35 U.S.C. § 103 are improper and should be withdrawn. Reconsideration is requested and it is submitted that claims 29, 30 and 38-40 are in condition for allowance, and such action is respectfully requested.

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